# Evaluating Decision-Making in Patients with Epilepsy

Submitted as part of Abbey Strazar's Undergraduate Thesis

May 2011

James W. McAuley, PhD, Advisor
Yun Jeong Lee, OSU P4 Student, Co-Investigator

**BACKGROUND**

The OSU Medical Center's Comprehensive Epilepsy Program is in a never-ending cycle of trying to improve the care of patients with epilepsy through asking patient preferences about their care [1], describing their perceived risk of epilepsy & its treatment [2] and ranking their concerns [3]. Many patients are seen in the outpatient epilepsy clinic on a routine basis. The goal for patients with epilepsy is "No seizures & No side effects". As antiepileptic drugs are the mainstay of treatment for nearly all epilepsy patients, much of what is done in clinic is to provide drug therapy recommendations with the goal to decrease seizure burden and/or lessen adverse drug effects. The ultimate decision-maker on whether they will follow the given advice is the patient and/or their family. Thus, as one member of the care team puts it, "We are in the advice business".

Experience over many years has demonstrated that when patients are given advice about changes to their drug therapy regimen, some follow it completely, some selectively follow it and others ignore it. Many patients follow advice, but three recent patient interactions have highlighted those who do NOT follow recommendations.

*Case 1* – A young woman with uncontrolled seizures who recently had drug access barriers removed. Despite this aid, she failed to take her medicines routinely and continued to have seizures. At her most recent routine follow-up visit, she was re-educated on the benefits of taking antiepileptic drugs. It is unclear why she does not follow recommended changes to her drug therapy regimen.

*Case 2* –A young professional woman of childbearing age who did not want to take daily folic acid supplementation which could help reduce the risk of teratogenicity if she became pregnant on her antiepileptic drug. Despite education from the practitioners, she stated she was not interested in "taking another pill".

*Case 3* – A young man with recent seizure activity who stated he did not want to take any medicines on a daily basis for his seizures. Yet he took alternative medicines daily to try and combat the seizures. Through intensive patient education, he agreed to try a new antiepileptic drug to be taken on a daily basis.

Needless to say, these patient interactions are puzzling. They highlight the need to learn more about how patients with epilepsy make drug-therapy decisions. As Lloyd and colleagues cite in their recent paper "to include patients' preferences in clinical decision making, there is a need for accurate information regarding the nature of the preference [4]." These authors provided some insight into patients with epilepsy's decision making when they compared the value that patients put on seizure control versus the adverse events of antiepileptic drugs. They measured patient preferences through a discrete choice method asking patients to make choices in scenarios where drugs could give seizure control vs. adverse effects. Not unexpectedly, their data suggests that patients with epilepsy have strong preferences for improving seizure control and reducing

adverse effects. Beyond this recent paper, there is little in the literature about how patients with epilepsy make decisions regarding their drug therapy choices. Our assumption is that patients fall somewhere along this scale when it comes to their drug-therapy decisions.

| 0=Never Follow Advice | 100=Always Follow Advice |
|---|---|

If we can learn more about how patients make drug therapy change decisions, perhaps we can "move" them further toward the right of the scale. The objective of this project is to determine why patients with epilepsy do or do not follow suggested advice to change their antiepileptic drug therapy.

**METHODS**

This is an anonymous, cross-sectional study assessing the drug-therapy decision making process of patients with epilepsy. If patients fit the following criteria they were asked at their Epilepsy clinic visit to be part of the study:

Inclusion Criteria

- Adult (>17 yrs) with a diagnosis of epilepsy
- Taking at least one antiepileptic drug
- Able to complete questionnaires
- Have at least one change to their current drug regimen suggested at their clinic visit
- Have a valid mailing or email address

Exclusion Criteria

- History of non-epileptic seizures
- Prisoner
- Pregnancy

After verbal consent was obtained (attached), the patients were asked to provide their mailing or email address. Patient tracking data were entered into a secure, online, interactive database that was set up by an Information Technology Specialist (A. Khurma) from the College of Pharmacy. Four weeks after their clinic visit, patients were sent a survey (attached) in the mail or an email was sent that included a link to an online survey (www.Qualtrics.com). The survey asks questions about whether or not they listened to their health care provider's advice.

If patients complete the survey online, the data is stored online in a password-protected file on www.Qualtrics.com. If patients completed the survey via mail, the returned surveys are manually entered into

the Qualtrics database. There are no tracking codes associated with any of the surveys, thus the data are not associated with patient data. We are doing this anonymously so patients are free to tell us their opinion without concern of connecting it back to them. Patients do not receive any compensation for completing the surveys, but they are told that for every completed survey, $5 will be donated to the local Epilepsy Foundation of Central Ohio by the Principal Investigator (Dr. McAuley).

## RESULTS

Although patient enrollment is not complete (target=100 patients), the data as of May 4, 2011 is presented below. As of May 4, 2011, we have recruited 55 patients. Fifty-one surveys have been sent invitations either by mail or email thus far. One patient's mailed survey was returned "undeliverable" due to a non-current address. To date we have received 28 responses for a response rate of 56%. Table 1. describes the demographics of the respondents. In addition to gathering pertinent demographic data, we asked patients to measure the impact of their seizures on their daily life (1 = "no impact" 10 = "impacts life tremendously"). The mean value was 5.96 ± 2.82.

**Table 1. Patient Demographics**

| **N** | **28** |
|---|---|
| **Gender** | 19 Females<br>7 Males |
| **Age** | Mean age 41.3 years ( range from 27-56 years) |
| **Age of first seizure** | Mean age 19.0 years ( range from 9 months-49 years) |
| **Type of seizures** | 9 "Grandmal"<br>3 Tonic Clonic<br>4 Partial Complex<br>5 Unsure of the name<br>5 Multiple forms |
| **Number of seizure medications** | 2.00 (±0.87) |
| **Have conditions beyond epilepsy** | 12 yes<br>13 no |
| **Total number of medications** | Mean number 4.36 (range from 1-8) |
| **Impact of seizure on everyday life ( 1=none, 10= a lot)** | 5.96 (±2.82) |
| **How long since last seizure?** | 9 within the last 30 days<br>9 1-6 months ago<br>2 6-12 months ago<br>5 more than 12 months ago |

Figure 1 describes what drug regimen changes were suggested at their clinic visit. Patients could choose more than one option.

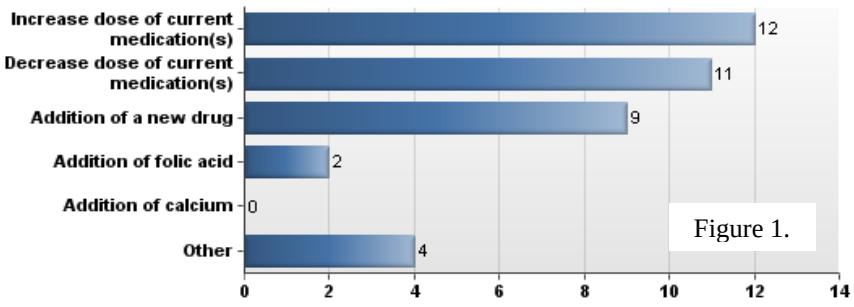


Figure 1.

As can be seen from the Figure 2, a majority of respondents (89.3%) stated that they followed the practitioner's advice when it came to making changes to their drug regimen. The patients who followed the suggestion stated that their reasoning had been that they wanted fewer seizures and fewer side effects. They also followed the recommendation to change their drug therapy because they truly trust their practitioner. Conversely, of the 3 people that answered no, their main reason to not listening was for fear of medication side effects and of pure annoyance to the change in their drug regimen.

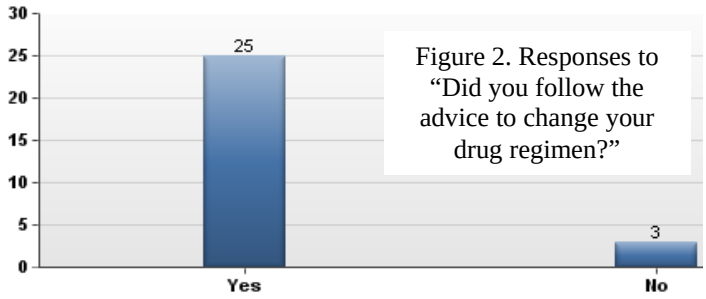


Figure 2. Responses to "Did you follow the advice to change your drug regimen?"

Because we are looking to increase the number of patients who follow their physicians advice verses patients who do not, we asked the question, "What are some reasons why you would follow your Practitioners recommendations?" The top 3 reasons were as follows:

1. They are Epilepsy Specialists
2. They took time to listen to me
3. Took the time to explain reasoning and have my best interest in mind

When asked what would be some reasons why you would not listen to your physician's advice the top 2 reasons were:

1. Cost
2. Did not understand the changes being made or physician did not listen to what I had to say

When asked if there was anything that the Outpatient Neurology Clinic could do to make its patients more receptive to the practitioners recommendations concerning their drug therapy, there seemed to be themes that emerged from the patient responses. Five patients suggested that the physician should explain changes and give detailed information about the drug that is in question. However, nine patients had similar statements that consisted of: "I am happy at the current time", or "nothing; my practitioner has done everything I've wanted".

Additionally, participants were asked to tell us their current status of adherence when it comes to drug-therapy changes. The number line ranged from 0 to 100 with 0 referring to "never follows advice" and 100 referring to "always follows advice." These results are graphically depicted in Figure 3 and are consistent information from similar questions.

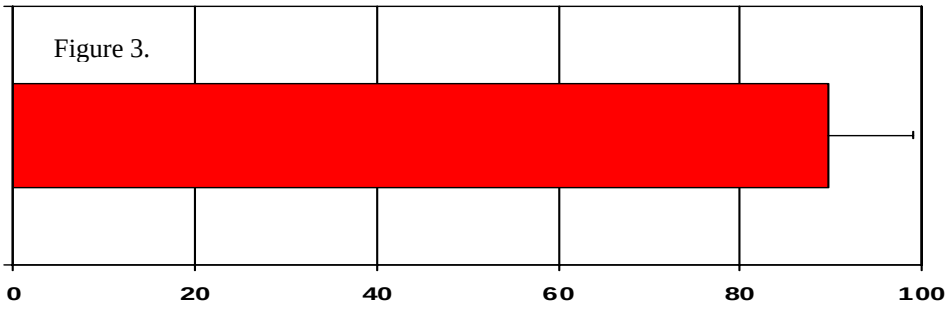


Figure 3.

**DISCUSSION**

After the challenging tasks of developing a research question, getting Biomedical Institutional Review Board (IRB) approval, and recruiting patients, this study has provided initial data to help us understand the decision-making process of patients. Within the past 8 months we have obtained enough data to begin assessing why certain patients follow their practitioners advice while others tend to stray away from their suggestions. Following IRB approval, I have had an active role in this study. I have continually met with Dr.McAuley to discuss topics that included: the direction of our research, responses thus far, and conflicts or misunderstandings that arose during clinic. For example, at a patient's previous clinic visit there was a change to their drug regime. However, once leaving the clinic they failed to follow their practitioner's advice. As a result, at their next appointment the practitioner decided to stick to his previous drug-therapy change and the patient finally agreed to cooperate. It was then up to us to discuss whether or not a change had been made to their drug regime and determine if they fit our criteria. It has also been my role to help recruit patients in clinic, enter returned mailed surveys properly into the Qualtrics database, and track the distribution of surveys 4 weeks after participants clinic visit.

We have previously suggested that there are three different domains of cooperation that a patient can fall under. One extreme is that the patient follows every suggestion that their practitioner utters, the other extreme is that they repeatedly tend to disagree and ignore their practitioner's recommendation. The middle of the two extremes is a patient who is inconsistent with listening to the practitioner's advice; this is our population of interest. The advice he/she will follow is based on their knowledge, or lack thereof, to the treatment in question. The significance of our survey is to use the results to develop different techniques to help practitioners understand their patient's needs and wants. This in effect might help persuade the middle domain patients to choose to listen to their practitioner verses ignoring their counsel. Though it is more of a challenge, we have not forgotten about the group that is less inclined to heed advice. We hope to learn things that may be beneficial to them as well.

As England and Evans stated in their paper, Active Patient Orientation, which is the extent to which patients participate in the decision-making process, monitor their own progress, and become educated about their disease state [5], might maximize therapeutic response and patient cooperation. By analyzing the responses to our questions we will be able to better understand patients' decision-making process and develop a technique to help persuade the "middle domain patients" to lean more towards the "yes domain". As it was stated in the RESULTS section, one of the main reasons that patients follow therapeutic recommendations is because the practitioner took time to listen and explain the reasoning to them. Likewise, the main reason why patients would NOT follow the alterations was because they did NOT understand the changes being made or the physician was not taking into consideration the concerns of the patient. The common trend is that patients

want to take part in the decision-making process and make sure that their opinions and concerns are being heard by their epilepsy specialist. Further research should help evaluate this concern. Once our target sample size of 100 has been obtained and every survey has been sent we can begin assessing the completed dataset and using our results to better understand our patients.

Our study is not without limitations. They include, but are not limited to, less than 100% response rate, incomplete data from those that responded, a cross-sectional approach, the use of a non-validated survey, and all the data are from patients seen at a single Comprehensive Epilepsy Program.

## POTENTIAL SIGNIFICANCE

By asking patients to provide anonymous feedback to us after their visit, we hope to learn more about how and why they make decisions regarding their drug therapy. With feedback from patients, we plan to then use that knowledge to improve patient care in our clinic and hopefully set an example for other health professionals.

## REFERENCES


1. McAuley JW, Miller MA, Klatte E, Shneker BF. Patients with Epilepsy's Perception on Community Pharmacist's Current and Potential Role in Their Care. Epilepsy & Behavior 2009;14:141-145.
2. Kucukarslan S, Reeves AL, McAuley JW. Patient Perceived Risk Associated with Epilepsy and Its Medication Treatment. Epilepsy & Behavior 2008;13:449–453.
3. McAuley JW, Elliott JO, Patankar S, Hart S, Long L, Moore JL, Shneker BF. Comparing Patients' and Practitioners' Views on Epilepsy Concerns: A Call to Address Memory Concerns. Epilepsy Behav. 2010;19:580-3.
4. Lloyd A, McIntosh E, Price M. The Importance of Drug Adverse Effects Compared with Seizure Control for People with Epilepsy: A Discrete Choice Experiment. Pharmacoeconomics 2005; 23: 1167-1181.
5. England S, Evans J. Patients’ Choices and Perceptions after an Invitation to Participate in Treatment Decisions. 1992; 34:1217-1225.

## CONSENT SCRIPT

The following information is explained to each eligible patient before they are asked to provide their mail or e-mail address.

---

*The purpose of this study is to learn more about the decision-making of patients with epilepsy. You will be sent a survey either by mail or e-mail asking you about how you approached the recent suggested changes to your medications. You will also be asked to answer questions to describe yourself. The survey will be sent out 4 weeks after your clinic visit today. The survey should take less than 15 minutes to complete and you will complete the survey only once.*

*We do not expect any risk to you for participating. As your responses will be anonymous, you will not directly benefit. But, patients with epilepsy in general may benefit because the practitioners in this clinic may learn how patients make decisions regarding medication changes. As a thank you for you sending back your survey or completing it online, we will donate $5 to the Epilepsy Foundation of Central Ohio for each completed survey. If you do not want to be part of the study, you can always tell us your concerns.*

*Your responses will not be shared with anyone outside the study. If you have any questions about the study, please don't hesitate to ask me or your practitioner. Your participation is voluntary; you may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. If you have any questions, you can call Dr. Jim McAuley at 614-292-9713.*

Hello OSU Epilepsy Clinic Patient,

We are continually striving to try and do a better job for our patients. At your recent clinic visit when we advised you to make a change to your drug regimen, you agreed to fill out a survey. Please answer the questions below and send the completed survey back to us in the postage-paid envelope included.

We do not expect any risk to you for participating. As your responses will be anonymous, you will not directly benefit. But, patients with epilepsy in general may benefit because the practitioners in this clinic may learn how patients make decisions regarding medication changes. As a thank you for you sending back your survey or completing it online, we will donate $5 to the Epilepsy Foundation of Central Ohio for each completed survey. If you do not want to be part of the study, you can always tell us how you make decisions about medication changes.

Your responses will not be shared with anyone outside the study. Your participation is voluntary; you may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. If you have any questions, please don't hesitate to contact Dr. Jim McAuley (614-292-9713 or mcauley.5@osu.edu or mailing address: OSU College of Pharmacy, 500 West 12th Ave, Columbus, OH 43210).

**SURVEY**

**1) Which of the following changes were recommended to you at your clinic visit 4 weeks ago? Choose all that apply.**

- o Increase dose of current medication(s)
- o Decrease dose of current medication(s)
- o Addition of a new drug
- o Addition of folic acid
- o Addition of calcium
- o Other

**2) Did you follow that advice?**

- o Yes **(please go on to question #3)**
- o No **(please skip to question #4)**

**3) What was the PRIMARY reason you DID follow that advice? (Please check only one)**

- o I want to have less seizures
- o I want to have less medication side effects
- o I trust my practitioner
- o Other

**4) What was the PRIMARY reason you DID NOT follow that advice? (Please check just one)**

- o Cost
- o Fear of medication side effects
- o Concern over drug interactions
- o Fear of seizures getting worse
- o I forgot what the change was
- o I'm happy with my current seizure control
- o Other

**5) What, if any, were OTHER reasons you did or did not follow the advice on making changes to your drug regimen?**

**6) Did you tell your Practitioner about your decision?**

- o Yes
- o No

**7) Why or why not did you decide to tell/ not tell your practitioner about your decision?**

**8) What are some reasons why you WOULD follow your Practitioners recommendations (check all that apply)?**

- o I received a handout to help me understand the changes
- o They took time to explain the changes
- o They took time to listen to me
- o They are an Epilepsy Specialist
- o They have my best interest in mind
- o Other

**9) What are some reasons why you WOULD NOT follow your Practitioner's recommendations (check all that apply)?**

They didn't understand or listen to me

- o I didn't understand what the changes were
- o I didn't understand why the changes were being made
- o I felt forced/threatened
- o Cost
- o I don't trust them
- o I had a bad experience with a past Practitioner
- o I read something on the internet
- o Other

**10) What can this clinic do to make you more receptive to our recommendations about your drug therapy?**

**11) Please circle the value below telling us where you think you are when it comes to accepting drug-therapy changes.**

Never=0% Always=100%

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 10 | 20 | 30 | 40 | 50 | 60 | 70 | 80 | 90 | 100 |

**12) In what year were you born? _____**

**13) I am:**

- o Female
- o Male

**14) How old were you when you had your first seizure? _____ years old.**

**15) What type of seizures do you have?**

| |
|---|
| |

**16) How many different seizure medicines do you take regularly?**

- o 1
- o 2
- o 3
- o 4 or more

**17) Do you have conditions beyond epilepsy?**

- o Yes
- o No

**18) What is the total number of all of your medications? _____**

**19) On a scale of 1 to 10 (1 being none and 10 being a lot), how much impact do your seizures have on your daily life? (Circle the value below)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**20) When was your last seizure?**

- o In the last 30 days
- o Between 1 and 6 months ago
- o Between 6 and 12 months ago
- o More than 12 months ago
- o I'm not sure

**THANK YOU!**